CLAIMS

Please cancel claims 5 and 6 without prejudice and substitute pending claim 1 and 7 with the corresponding amended claims 1 and 7, as shown below:

1. (Thrice Amended) A stable, aerosolizable composition that is pharmaceutically suitable for rapid bronchial delivery to a lung of a subject, the composition comprising a therapeutically effective amount of delta-9-tetrahydrocannabinol in a pharmaceutically-acceptable semiaqueous solvent comprising volumetric ratios of 10-70 parts of ethanol, 10-30 parts of water and >20-80 parts of propylene glycol having a combined total of 100, provided that:

(i) upon aerosolization the composition has a mean mass median aerodynamic diameter in the range from about 1 up to about 10 μM; and

(ii) the ratio of the ethanol, water and propylene glycol produces a stable clear solution near the solubility point of the delta-9-tetrahydrocannabinol such that upon administration to the lung, the partitioning of the delta-9-tetrahydrocannabinol from the solvent is enhanced so as to reach the bloodstream.

2. A composition as defined in Claim 1 wherein the amount of delta-9-tetrahydrocannabinol comprises from about 0.1 to about 200 mg delta-9-tetrahydrocannabinol/mL of the solvent.

3. A composition as defined in Claim 2 wherein the amount of delta-9-tetrahydrocannabinol comprises from 0.1 to 25 mg delta-9-tetrahydrocannabinol/mL of the solvent.

4. A composition as defined in Claim 2 wherein the amount of delta-9-tetrahydrocannabinol comprises 50 mg delta-9-tetrahydrocannabinol/mL of the solvent.

7. (Amended) A composition as defined in Claim 1 wherein the volumetric ratios of ethanol : water : propylene glycol are selected from those in the range of from 10 – 70 : 10 : >20 – 80, respectively, having a combined total of 100.

8. A composition as defined in Claim 7 wherein the volumetric ratios of ethanol : water : propylene glycol are 35 : 10 : 55, respectively, having a combined total of 100.

9. A sterile and/or preserved sealed unit– or multi-unit dosage form of delta-9-tetrahydrocannabinol comprising a container and a stable composition for rapid delivery by inhalation to the lungs and subsequently to the bloodstream, as defined in Claim 1.

10. A sterile and/or preserved sealed unit- or multi-unit dosage form as defined in Claim 9 wherein said container comprises Type I Amber Glass with a suitable liner.

11. The composition of claim 1, wherein the mean mass median aerodynamic diameter is from about 1μM to about 3 μM.

12. The composition of claim 1, wherein the alcohol is selected from the group consisting of ethanol and isopropanol.

13. The composition of claim 1, wherein the glycol is selected from the group consisting of propylene glycol, polypropylene glycol, and polyethylene glycol.

14. The composition of claim 1, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.05% to about 15%, by weight, of the composition.

15. The composition of claim 14, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.02% to about 5%, by weight, of the composition.

16. The composition of claim 15, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.1% to about 4%, by weight, of the composition.

17. The composition of claim 1, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.01 mg to about 100 mg per kilogram of body weight of the subject.

18. The composition of claim 17, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.025 mg to about 35 mg per kilogram of body weight of the subject.

19. The composition of claim 18, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.05 mg to about 5 mg per kilogram of body weight of the subject.

20. The composition of claim 1, further comprising an agent selected from the group consisting of an anti-oxidant, surfactant, buffer, pH adjusting agent, bacteriostatic agent, stabilizer, sodium chloride, and preservative.

21. The composition of claim 1, wherein the composition is administered to the subject one to five times a day.

22. The composition of claim 1, wherein the subject is a human.

REMARKS

Claims 1 and 7 are amended herewith. Support for these amendments can be found at least on page 12, lines 21-29. Applicant respectfully submits no new matter has been added by way of these amendments.

Claims 1 and 7 have been amended as recommended by the Examiner in the March 6, 2002 interview. Applicant respectfully submits that these amendments where made to more